

Docket No.: 1217-0173PUS1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Annie BARDAT et al.

Application No.: 10/563,620

Confirmation No.: 1914

Filed: January 6, 2006

Art Unit: 1653

For: METHOD FOR STABILIZING A
CRYOPRECIPITATE OF PLASMATIC
PROTEINS FOR BEING SUBJECTED TO A
VIRAL INACTIVATION THERMAL
TREATMENT

Examiner: Not Yet Assigned

LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Subsequent to the filing of the above-identified application on January 6, 2006, attached hereto is an English translation of the International Preliminary Examination Report (Form PCT/IPEA/409) that should be made of record in the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or to credit any overpayment to Deposit Account No. 02-2448 for any

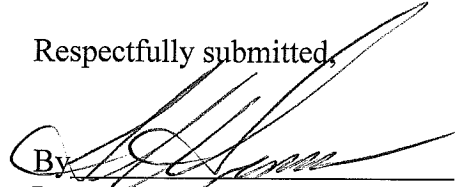
Application No.: 10/563,620

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additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Dated: June 19, 2006

Respectfully submitted,

By 

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Attachment(s)

PATENT COOPERATION TREATY

Translation


PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/FR2004/001788	International filing date (day/month/year) 08.07.2004	Priority date (day/month/year) 09.07.2003
International Patent Classification (IPC) or national classification and IPC A61K38/36, A61K38/37, A61K47/18, A61K47/12, A61L2/00, C07K14/75		
Applicant LABORATOIRE FRANCAIS DU FRACTIONNEMENT ET DES ...		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.	
2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.	
<input checked="" type="checkbox"/>	This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
These annexes consist of a total of <u>2</u> sheets.	
3. This report contains indications relating to the following items:	
I <input checked="" type="checkbox"/>	Basis of the report
II <input type="checkbox"/>	Priority
III <input type="checkbox"/>	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV <input type="checkbox"/>	Lack of unity of invention
V <input checked="" type="checkbox"/>	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI <input type="checkbox"/>	Certain documents cited
VII <input type="checkbox"/>	Certain defects in the international application
VIII <input type="checkbox"/>	Certain observations on the international application

Date of submission of the demand 09.05.2005 (May 9, 2005)	Date of completion of this report 25.07.2005 (July 25, 2005)
Name and mailing address of the IPEA/EP  Office européen des brevets D-80298 Munich Tél. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Giménez Miralles, J Telephone No. +49 89 2399-8655

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/FR2004/001788

I. Basis of the report

1. This report has been drawn on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.)*:

- ☐ the international application as originally filed.
- ☒ the description, pages 1-24, as originally filed,
 pages _____, filed with the demand,
 pages _____, filed with the letter of _____,
 pages _____, filed with the letter of _____.
- ☒ the claims, Nos. _____, as originally filed,
 Nos. _____, as amended under Article 19,
 Nos. _____, filed with the demand,
 Nos. 1-21, filed with the letter of May 9, 2005 (09/05/2005),
 Nos. _____, filed with the letter of _____.
- ☒ the drawings, sheets/fig _____, as originally filed,
 sheets/fig _____, filed with the demand,
 sheets/fig _____, filed with the letter of _____,
 sheets/fig _____, filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. 555

PCT/FR 2004/001788

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims		YES
	Claims	1-21	NO
Inventive step (IS)	Claims		YES
	Claims	1-21	NO
Industrial applicability (IA)	Claims	1-21	YES
	Claims		NO

2.

Point V

1. Relevant documents are identified as being D1 to D13, as cited in the International Search Report (ISR) (D1 is the first document cited, D2 the second etc.)
2. Citations and explanations based on the statement related to Novelty (N), Inventive Step (IS), and Industrial Application (PA) (R.43bis.1(a)(i) and 43bis.1(b) PCT) :

2.1 Claim 1 (method) and 17 (product obtainable by this method)

(N) The subject matter of independent claims 1 and 17 do not comply the requirements of Novelty defined by the Article 33(2) PCT.

The document D3 anticipates the thermal treatment (80°C, 72 h) of a freeze-dried form of cryoprecipitable proteins (factor VIII) including a stabilizing formulation comprising a mixture of arginine, citrate and hydrophobic amino acids, like leucine, isoleucine, valine or phenylalanine (mixture of amino acids "Synthamin 17") (see relevant parts indicated in the ISR).

The document D4 anticipates the thermal treatment (60°C, 15 days) of a freeze-dried form of cryoprecipitable proteins (G-CSF) including a stabilizing formulation comprising a mixture of arginine, citrate and hydrophobic amino acids, like leucine, isoleucine, valine or phenylalanine (see relevant parts indicated in the ISR).

The feature defined in the instant dependent claim 19 is only a searched result, and cannot then restrict the scope of the claimed subject matter with regard to documents D3 and D4 (see Guidelines PCT, III-4.7)

(IS) The subject matter of claims 1 and 17 does not involve an inventive step as defined by the Article 33(3) PCT, for the reasons hereunder mentioned. Moreover, documents D7 to D12 could be relevant for the assessment of the inventive step.

(PA) The subject matter of independent claims 1 and 17 is susceptible of industrial application as defined by Article 33(4) PCT.

2.2 Claim 20 (stabilizing formulation)

(N) The subject matter of independent claim 20 do not comply the requirements of Novelty defined by the Article 33(2) PCT.

Documents D1 to D6 anticipate freeze-dried forms of cryoprecipitable proteins (factor VIII, fibrinogen, factor XIII, G-CSF etc.) including a stabilizing formulation comprising an association mixture of arginine, citrate and a hydrophobic amino acid, like leucine, isoleucine, valine or phenylalanine (see relevant parts indicated in the ISR).

A specific use of the stabilizing association (for example in a freeze-dried intended to be subjected to a virus inactivation thermal treatment) does not establish the novelty of the claimed subject matter (stabilizing formulation), because known in the art D1 to D6 compositions are effectively in a form which is appropriate to the use indicated in the instant claim 20 (see Guidelines PCT, III-4.8 and IV-7.6).

(IS) The subject matter of claim 20 does not involve an inventive step as defined by the Article 33(3) PCT, for the abovementioned reasons.

(PA) The subject matter of independent claim 20 is susceptible of industrial application as defined by Article 33(4) PCT.